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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/042,583	03/17/1998	JIAN NI	PF366	5224
28730	7590	12/03/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			KAUFMAN, CLAIRE M	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/042,583

Applicant(s)

NI, ET AL.

Examiner

Claire M. Kaufman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) see attached is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) see attached is/are allowed.
- 6) ☒ Claim(s) see attached is/are rejected.
- 7) ☒ Claim(s) see attached is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/3,6/6/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2003, has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Declaration***

The Declaration filed on 08/20/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejections under 35 USC 102(e) and 103 relying on the US Patent 6,072,047 reference. See the response to arguments for the rejections maintained below.

### ***Claim Rejections - 35 USC § 102***

Claims 492-495, 507-508, 518-523, 535-541 and 608-611 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,072,047, cited by Applicants, for the reasons set forth in the previous Office action (paper #34) on pages 5-6.

Applicants argue that the 1.131 Declaration by the instant inventors with attached exhibits is sufficient to overcome the rejections under 35 USC 102 and 103 because it supports Applicants' assertion that prior to March 12, 1997, they were in possession in the USA of at least the sequence of the cDNA and full encoded protein as well as description of the receptor domains and identification of the protein as a member of the Tumor Necrosis Factor (TNF) receptor family. The argument has been fully considered, but is not persuasive. Even though Applicants have presented evidence of possession of the cDNA and encoded protein sequence prior to March 12, 1997, one would not have known how to use either the DNA or protein.

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Although the protein was identified as a member of the TNF receptor family and possessed a death domain, not all members of the receptor family share the same function(s) or bind the same ligand(s). Despite the structural relationship within the TNF receptor family, there is great diversity of function and ligand specificity (see Figures 1 and 2 of reference Smith et al., Cell 76:959 (1994) attached as Exhibit C to the Declaration of 8/20/03). Without the ligand of a receptor or an activity which is known usable in the absence of a ligand, one would not know how to use a receptor. Because the Declaration and accompanying evidence does not fulfill the requirement of how to use under 35 USC 112, first paragraph, it is not sufficient to antedate the '047 patent and does not teach as much as the '047 priority application, which identified the protein as a TRAIL binding receptor.

Applicants argue that *In re Wertheim* is applicable and in view of *Wertheim*, none of the patent claims of the '047 patent can receive priority back to March 12, 1997. For the reasons set forth in the Advisory Action of 3/21/03, this argument is not persuasive. The priority application of the '047 patent fully supports what is claimed in the '047 patent and fully discloses what is claimed in the instant application. It is maintained that '047 is properly applied as art under 35 USC 102(e) and 103.

### ***Claim Rejections - 35 USC § 103***

Claims 492-552 and 608-622 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,072,047, for the reasons set forth in the previous Office action (paper #34) on pages 6-8.

Claims 287-299, 319, 326-339, 351, 353-373, 389, 391-415, 431, 433-458, 476, 478-491, 553-565 and 567-594 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,072,047, for the reasons set forth in the previous Office action (paper #34) on pages 8-10.

Applicants argument which pertain to the rejections under both 35 USC 102 and 103 have been addressed above.

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Applicants argue that for the rejection under 35 USC 103, the February 13, 1997, priority document of '047 is not sufficient to sustain a *prima facie* case of obviousness on its own. This argument is moot since the 1.131 Declaration is insufficient to overcome the rejection. Further, the February 13, 1997, priority application did not teach the full-length encoding DNA or protein and, therefore, could not stand alone to establish obviousness and was not intended by the examiner to do so. The February 1997 document was discussed only in terms of describing a function and use for the receptor protein disclosed in the '047 patent and March 12, 1997 priority document.

### ***Conclusion***

Claims 320-325, 352, 390, 432, 477 and 566 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 300-318, 340-350, 374-388, 416-430, 459-475 and 595-607 remain allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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CONTINUATION OF OFFICE ACTION SUMMARY PTOL-326

4) Claims 287-432, 434-442, 446- 493, 495-503, 506-521, 523-531, 535-539, 541-549, 553-608, 611-619 and 622 are pending.

5) Claims 300-318, 340-350, 374-388, 416-430, 459-475 and 595-607 are allowed.

6) Claims 287-299, 319, 326-339, 351, 353-373, 389, 391-415, 431, 434-442, 446-458, 476, 478-493, 495-521, 522-531, 535-539, 541- 549 553-565, 567-594 and 608, 611-619 and 622 are rejected.

7) Claims 320-325, 352, 390, 432, 477 and 566 are objected to.

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791 (changing to (571)272-0873 on 01/22/04). Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564 (changing to (571)272-0871 on 01/22/04).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. **NOTE:** If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 25, 2003



**LORRAINE SPECTOR  
PRIMARY EXAMINER**